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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,695	04/19/2001	Naomi Balaban	3908P2538	1785

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,695	BALABAN, NAOMI	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed April 6, 2005 has been entered. The examiner acknowledges the amendment to the specification and drawings. Claims 1 and 5 have been amended. Claims 2-4 and 6 have been cancelled. Claims 1and 5 are under consideration in this office action.

Priority

2. Applicants traverses the Examiner's finding that applicants' have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: because the claims in the instant continuation-in-part application recites a feature, i.e. an isolated RAP polypeptide having an amino acid sequence of SEQ ID NO:13 (claim 1) and a vaccine comprising the RAP polypeptide of claim 1 or an antigenically effective portion thereof, and a pharmaceutically acceptable carrier (claim 5) which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent application. This feature has been first introduced and adequately supported in the instant continuation-in-part application and thus such claims are entitled only to the filing date of the instant application.

Applicants' assert that U.S. Patent 6,291,431 (the parent application Serial No. 09/054,331) for which the instant application claims the benefit under 35 U.S.C. 120 teaches an isolated RAP polypeptide having an amino acid sequence of SEQ ID NO:13) and a vaccine comprising the RAP polypeptide of claim 1 or an antigenic ally effective portion thereof, and a pharmaceutically acceptable carrier.

Applicants' point to col. 12, lines 50-55 stating that U.S. Patent 6,291,431 incorporates the Balaban (Science, 1998) article by reference. However there is no reference to the Balaban (Science, 1998) article within the specification. At best, the specification refers to Balaban et al., FEMS Microbiol. Letts. Vol. 133, 155 (1995) and Balaban et al., PNAS. Vol. 92, 1619 (1995), however this incorporation is insufficient to overcome the fact the 1998 article was not cited and cannot therefore be the basis of support. Thus, the fact that col. 12, lines 50-55 states that all publications and patent applications cited in this specification are incorporated by reference is irrelevant, since the patent does not cited this publication. Moreover, applicants' assertion that WO 99/32133 was incorporated by reference is not persuasive for the reasons above.

U.S. Patent 6,291,431 makes no reference to an isolated RNAIII activating protein having an amino acid sequence of SEQ ID NO:13, neither is there a reference to any amino acid sequence having 279 amino acids. There is no reference to said polypeptide being comprised within a vaccine or any antigenically effective portion of that polypeptide being comprised within a vaccine. Therefore, contrary to applicants' statements, US Patent 6,291,431 failed to teach an isolated RAP polypeptide having an amino acid sequence of SEQ ID NO:13 and a vaccine comprising the RAP polypeptide or an antigenically effective portion thereof, and a pharmaceutically acceptable carrier. Applicants' have failed to specifically point to by page and line number, support for these claims. Therefore, the priority to the earlier filing date under 35 U.S.C. 120 is denied.

Drawings

3. The drawings are still objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 5 refers to sequences without sequence identifying numbers being described within the figure itself or the brief description of the drawings within the specification. It is acknowledged that amendment now refers to a deposit number as identification, however the deposit number is not sufficient. Instead, applicants should refer to the appropriate sequence identification number and amend the sequence listing if necessary. Therefore, appropriate correction is required.

Withdrawal of Objections and Rejections

4. The following objections and rejection have been withdrawn in view of applicants' amendments:

a) The objection of claims 1 and 5; and

b) The rejection of claims 1 and 5 under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claim 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons already of record. The rejection was on the grounds that the written description in this case fails to set forth a specific antigenically effective portion thereof. Applicants' assert that only the polypeptides described by SEQ ID NO:1-4 qualify as antigenically effective portions. However, the claims are so broad that the vaccine encompasses more than SEQ ID NO:1-4. The claim encompasses any antigenically effective portion regardless of the identity and actual structure of amino acid sequence. The

MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606;

In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is not a sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli,* the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872 F.2d at 1012, 10 USPQ2d at 1618.

The specification does not provide a sufficient number of representative species that would qualify as an antigenically effective portions of the claimed invention. Instead, the description within the specification is limited to the teaching at page 12 of the instant specification which fails to disclose that these peptides have the ability to treat or prevent a Staphylococcal infection or disease. It is unquestionable that the claims are broadly generic with respect all possible portions of polypeptides encompassed within the claims. The possible structural variations are limitless. It must not be forgotten that the MPEP 2163 states that if

a biomolecule is described only by a functional characteristic, the written description is deficient, even when accompanied by a method of obtaining the claimed sequence. Here, the claims recite some functional characteristics, i.e., being antigenically effective. The claims lack written description because there is no disclosure of a correlation between function and structure. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any other examples.

There is no disclosure what regions within the sequences provide for being antigenically effective. There is merely a general outline drawn to these peptides may prevent or treat Staphylococcal infections while not applying directly to the instant invention. Thus the specification fails to provide an adequate written description of a vaccine comprising an antigenically effective portion and a pharmaceutically acceptable carrier. This demonstration is required for the skilled artisan to be able to use the claimed vaccine. In view of the specification failure to disclose the identity or adequately describe the antigenically effective portions having the instantly claimed characteristics, a skilled artisan would be required to *de novo* locate, identify and characterize the claimed nucleic acid sequences with the recited abilities. Therefore the full breadth of the claim fails to meet the written description provision of 35 USC 112, first paragraph and the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Balaban et al., (Science 1998) is maintained for reasons already of record. The rejection was on the grounds that Balaban et al., teach a vaccine comprising the RAP polypeptide or an antigenically effective portion thereof, and an adjuvant which is pharmaceutically acceptable carrier.

Applicants argue that Balaban et al., Science article published in 1998 is not citable against the pending application. However, as previously discussed the instant application fails to receive the benefit of priority to the earlier filing date under 35 U.S.C. 120. As previously discussed, there is no teaching of an isolated RAP polypeptide having an amino acid sequence of SEQ ID NO:13 or a vaccine comprising the polypeptide or an antigenically effective portion and a pharmaceutically acceptable carrier.

Balaban et al., teach the purification the RAP protein and its use with a vaccine. Therefore, the teaching of Balaban et al., meets the limitations of the claims.

7. The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Balaban et al., (WO 99/32133) is maintained for reasons already of record. The rejection was on the grounds that Balaban et al., teach a vaccine comprising the RAP polypeptide or an antigenically effective portion thereof, and an adjuvant which is pharmaceutically acceptable carrier.

Applicants argue that Balaban et al., (WO 99/32133) is not citable against the pending application. However, as previously discussed the instant application fails to receive the benefit of priority to the earlier filing date under 35 U.S.C. 120. As previously discussed, there is no teaching of an isolated RAP polypeptide having an amino acid sequence of SEQ ID NO:13 or a vaccine comprising the polypeptide or an antigenically effective portion and a pharmaceutically acceptable carrier.

Balaban et al., clearly teach the instantly claimed vaccine, therefore applicants' arguments are not persuasive and the rejection is maintained.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 6, 2005

L. F. Smith

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